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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,118	11/25/2003	Cheng Shine Hwang	00216-654001 / H-254 (Ka	6141

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/721,118	HWANG ET AL.	
	Examiner	Art Unit	
	GINA C. YU	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 4-46* is/are pending in the application.

4a) Of the above claim(s) *5-7,9-28 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8 and 29-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on June 24, 2009, PROSECUTION IS HEREBY REOPENED.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

In this Office action, claim rejection made under 35 U.S.C. § 103 (a) as being unpatentable over Billoni et al. (Aeta Derm. Venereol. 2000, 80:329-334) in view of Monneret et al. (J. of Immunol., 2002, 168:3563-3569) is withdrawn in view of applicant's remarks. New rejections are set forth below.

Election/Restrictions

In response to species requirement made on March 23, 2007, applicant has elected 15-deoxy- $\Delta^{12,14}$ –PGD_2 of claim 8 as the specific prostaglandin DP receptor

agonist. The subject matter of claim 8 is found to be allowable; examiner next elects 15-deoxy- $\Delta^{12,14}$ –prostaglandin J_2 of claim 27.

Therefore, claims 1, 2, 4, 8, 27, 29-45 are examined on the merits in this Office action. Claims 5-7, 9-28 and 46 remain withdrawn from consideration.

Allowable Subject Matter

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 29-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific PGD2 and analog compounds disclosed in the working examples, does not reasonably provide enablement for the entire genus of prostaglandin DP receptor agonists.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary

experimentation is "undue" include, but are not limited to: a) the breath of the claims; b) the nature of the invention; c) the state of the prior art, the level of one of ordinary skill; d) the level of predictability in the art; e) the amount of direction provided by the inventor; f) the existence of working examples; and g) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

The breath of the claims

Claim 1 is representative of the instant invention and directed to a method of reducing mammalian hair growth by selecting an area of skin including hair follicles from which reduced hair growth is desired, and applying to the said area of skin a dermatologically acceptable composition comprising **an agonist of prostaglandin DP-receptor** in an amount effective to reduce hair growth. Claim 43 is directed to an analogous method which uses a compound selected from **prostaglandin D2, analogs of prostaglandin D_2, PGJ_2 or an analog of PGJ_2.** Claim 44 is directed to an analogous method which uses **a compound that activates DP receptor signal transduction pathway.** Claim 45 is directed to an analogous method which uses **a compound that inactivates prostaglandin D_2 metabolic pathway.**

The inventions of claims 1 and 44 use the entire genus of the agonists of PGD receptor, which include PGD_2 analogs, derivatives, PGD_2 metabolites and their analogs. See applicant's spec. p. 4, lines 15 – 16.

The nature of the invention

The present invention is directed to a method of controlling unwanted hair growth by locally administering the entire genus of the agonists of PGD receptor, which include PGD_2 analogs and PGD_2 metabolites and their analogs.

The state of the prior art

Agonists of prostaglandin DP receptors were known in the art, as admitted by applicant in specification p. 4, lines 15 -24; Table 1. Prostaglandin D_2 analogs and derivatives, its sequential metabolites and their analogs also were known at the time of the present invention.

However, prior arts also teach that some of the agonists of prostaglandin DP receptors disclosed by applicant (e.g., BW245C and BW246C) have been used in a hair **growth promoting** agent. See Michelle et al. (US 2004/0052760 A1) [0164]. assigned to the same assignee of the present invention. According to applicant's own disclosure, BW245C and BW246C are PGD_2 analogs. See spec. p. 4, Table I, lines 4-5. Midorikawa (JP 203155218 A, abstract) also teaches prostaglandin D and derivatives thereof is used in a hair **growing** composition.

The level of predictability in the art

Since the prior utility of prostaglandin DP receptors was known to induce the opposite effect of the present invention, the efficacy of the all of the compounds encompassed by the present invention would have been highly unpredictable to a person of ordinary skill in this art.

The amount of direction provided by the inventor

The present specification discloses examples of PGD_2 analogs, but suggests ***any*** of the known agonist of prostaglandin DP receptor would be suitable for the purpose of practicing the present invention.

The existence of working examples

Specification pages 11-13 show in vitro human hair follicle growth assay using seven compounds that are PGD_2 or its analogs (i.e., PGD_2, 15-deoxy- delta $^{12, 14}$-PGD_2, 16,16-dimethyl PGD_2, 15(S)-15 methyl PGD_2, 17-phenyl trinor PGD_2, 11-deoxy-11-methylene PGD_2, 15(R)-15-methyl PGD_2).

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Since the prior art suggests not all agonists of prostaglandin DP receptor are effective for reducing hair growth, and in fact have been used for growing hair, it would be inevitable for a skilled artisan to undergo undue experimentation to test the efficacy of the prostaglandin DP receptors which are not disclosed in the working examples of the applicant's specification.

In conclusion, since prior arts teaches prostaglandin D and at least some of PGD_2 analogs have been used for hair growing agents, applicant's claim that all PGD receptor agonists and PGD_2 analogs are useful for hair growth reduction directly conflicts with what was known to a person of ordinary skill in the art at the time of the present invention. Therefore, undue experimentation is necessary to test the efficacy of prostaglandin DP receptors or compounds that activates DP receptor signal transmission pathway which have not been tested according to the applicant's

disclosure. Applicant's specification enables only those PGD_2 and the analogs in the working examples and fails to enable the full scope of the present claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 4, 27, 29-45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Needlemen et al. (US 2003/0220374 A1) in view Rosenfield (US 6004751).

Needlemen discloses hirsutism can be treated by administering to the subject with PPAR peroxisome proliferators-activated receptors (PPARs) – γ agonists in an effective dosage. See p. 6, Table 2, ciglitazone, danglitazone, englitazone, pioglitazone, roniglitazone, and troglitazone. The reference indicates 15-deoxy- $\Delta^{12,14}$ – prostaglandin J_2 (15d-J_2), a PGJ_2, PGD_2 metabolite and a PPAR– γ activator, causes marked growth inhibition of hepatocellular cancer cells and suggests other PPAR– γ agonists may be useful in the treatment of a variety of cancers.

One would not immediately envisage using the claimed compound for treating hirsutism. However, Needleman teaches that (PPARs) – γ agonists are used to inhibit cell growth.

Rosenfield teaches PGD_2 is a major product of cyclooxygenase in a variety of tissues and cells and readily undergoes dehydration in vivo and in vitro to yield prostaglandins of the J_2 series (PGJ_2). The reference teaches the members of the PGJ_2 series are known to exhibit inhibition of cell cycle progression, suppression of viral

replication, induction of heat shock protein expression and stimulation of osteogenesis. See col. 12, lines 40 – 51.

Although Needlemen and Rosenfield do not disclose PGJ2 or its analogs specifically used in treating hirsutism or reducing hair growth, the references indicates that the PGJ_2 and other PPAR– γ agonists have been known to inhibit cell cycle progression or growth. Since Needlemen discloses PPAR – γ agonists are known to be effective in treating excess hair growth, a person of ordinary skill in the art would have had a reasonable expectation of success in using PGJ_2 to treat hirsutism. Since applicant defines prostaglandin DP receptor agonists to include PGJ_2, instant claims 1 and 4 are met.

Response to Arguments

Applicant's arguments filed on June 24, 2009 have been fully considered but they are moot in view of the new grounds of rejection(s) in part and not persuasive in part.

Applicant asserts the previously cited reference, Billoni et al. focuses on "an entirely different receptor family", and further states that the DP receptor structure of the claims and the PPAR receptor family of the prior art are different. The argument is unpersuasive, as it is well that PGJ, 15-D ^{12,14}-PJ_2 are endogenous activators of peroxisome proliferator activated receptors. See, Corton et al. Annu. Rev. Pharmacol. Toxicol. 2000, 40:491-517, p. 498, Table 3 (cited by applicant). Applicant has also admitted that DP receptors include PGD2 and its analogs, which in turn include PGJ_2. Therefore applicant's assertion that there is no correlation between PPAR family and prostaglandin DP receptor agonists is erroneous.

Applicant asserts Billoni discloses the effect of clofibrate, a PPAR-α agonist, in hair growth modulation but does not specifically indicate the effect of 15d-J_2 or PPAR-–γ agonists. The argument is moot in view of the new grounds of rejection discussed above.

Conclusion

Claims 1, 2, 4, 27, 29-45 are rejected.

Claim 8 is objected to and allowable if rewritten to overcome the scope of enablement rejection discussed above.

Claims 5-7, 9-25, and 46 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1611